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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,460	02/06/2002	Roger Craig	18747/2012	8894

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,460	CRAIG ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *15-20 and 22-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Primary Examiner Scott D. Priebe, Ph.D., Group Art Unit 1632.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 15-20 and 22-26 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response received on 10/14/03.

This application contains claims 15-20 and 22-26 drawn to an invention nonelected with traverse in the reply filed 10/14/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

Claims 1-14 and 21 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth in the Office action of 5/18/04. The claim(s) contains subject matter which was not described in the specification in such a way

as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Upon reconsideration and in view of Applicant's arguments, the specification is deemed to enable the invention for embodiments wherein the regulatory region is the promoter of an insect vitellogenin gene, such as the Yp genes of *Drosophila* or the VG1 or VG2 genes of medfly, which mediate sex-specific expression in females, but does not enable embodiments of the invention wherein the regulatory region is from any other gene.

Claims 1-14 and 21 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in the Office action of 5/18/04. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 11/22/04 have been fully considered but they are not persuasive. The issue in both rejections is whether the description and enabling disclosure bears reasonable correlation to the scope of the claimed subject matter with respect to the sex-specific regulatory region required for the invention. The specification describes using the known *Drosophila melanogaster* Yp1 (yolk protein 1) promoter, which mediates expression in the fat bodies of female flies in both transgenic *D. melanogaster* and in medfly. The yolk proteins of *D. melanogaster* are the vitellogenins of this species. The specification also teaches that for control of medflies that the known promoter of the VG1 (vitellogenin 1) or VG2 (vitellogenin 2) genes

could be used. The specification is deemed to meet the written description and enablement requirements for embodiments limited to a female-specific regulatory region of an insect vitellogenin gene.

However, the specification fails to meet the written description and enablement requirements for embodiments requiring female-specific regulatory regions of other genes, or for embodiments requiring any male-specific regulatory region. There is no dispute that the specification does not teach any other promoter mediating female-specific expression than those of the *D. melanogaster* and medfly vitellogenin genes, and does not teach any promoter mediating male-specific expression. With respect to both rejections, Applicant argues that other sex-specific promoters were known in the prior art. Applicant is respectfully reminded that the written description and enablement requirements must be met by the specification at the time the application was filed. In the instant case, priority for the invention is sought to Aug. 1999, when the British applications and the provisional US application were filed. Thus, the requirements must have been met as of the Aug. 1999 filing dates of the priority documents.

Applicant cites Exhibits B-F attached to the declaration filed 11/22/04 under 37 CFR 1.132 as evidence that other sex-specific promoters were known at the time the instant application was filed. Exhibits B and C show that the promoter regions for vitellogenin genes from medfly and some mosquitoes where known in the prior art. However, the specification is deemed to enable and adequately describe embodiments employing a generic female-specific transcriptional regulatory region of a vitellogenin gene.

Exhibits D and E are cited for showing that the female-specific splicing regulatory elements of the *D. melanogaster doublesex* gene were known. First, Exhibit D (published in

2000) is not prior art. Second, the specification does not mention the splicing regulatory elements of the *doublesex* gene. Third, the specification (pages 3-4 and 11) explains that "regulatory region" refers promoters or enhancers the regulate sex-specific transcription, not that regulate post-transcriptional mRNA splicing, as does the *doublesex* splicing regulatory element. Therefore, Exhibits D and E are not dispositive.

Komitopoulou et al. (Exhibit F) is cited as showing that other sex-specific regulatory regions from medfly were known in the prior art. Komitopoulou is a review that was published about five years after the priority applications were filed (and about 3 years after the instant application was filed). The review discusses results published in 2000 on recombinant promoters of two male-specific medfly genes, *MSSP-α2* and *MSSP-β2* (pages 150-152). While the recombinant *MSSP-α2* promoter was found to direct male-specific transgene expression in medfly, the *MSSP-β2* did not. This indicates that an endogenous sex-specific promoter may lose the ability for sex-specific expression when used in a recombinant or transgenic construct. Both recombinant medfly promoters functioned in *D. melanogaster* but not in a sex-specific fashion. The review indicates that sex-specific expression of genes is poorly conserved between species, i.e. a gene that is expressed sex-specifically in one species of insect is often not expressed sex-specifically when introduced into another insect species. The review discusses female-specific expression of vitellogenin genes, chorion genes and ceratotoxin genes of medfly and *Drosophila*. However, it appears that only the vitellogenin promoters and one chorion gene promoter from *Drosophila* had been well characterized in the prior art. The medfly *s36* promoter was published in 2001. The review indicates that functional studies were needed to identify the sex-specific regulatory elements of the ceratotoxin genes. The claims are not limited to controlling

Drosophila and medfly populations, and the review does not indicate that sex-specific promoters for other insects were widely known in the prior art.

The courts have held that a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. Tossing out the germ of an idea does not constitute an enabling disclosure. While every aspect of a generic claim need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable the skilled artisan to understand and carry out the invention. It is true that a specification need not disclose what is well known in the art. However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement under 35 USC 112, first paragraph. However, when there is no disclosure of any specific starting material or of any of the conditions under which the process can be carried out, then undue experimentation is required and there is a failure to meet the enablement requirement. See *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 101, 1005 (CA FC, 1997).

The Federal Circuit and the Board have repeatedly held (*Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*,18 USPQ2d 1016 (CA FC, 1991); *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993); *Fiddes v. Baird*, 30 USPQ2d 1481 (BPAI 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)) that an adequate written description of a nucleic acid requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it, irrespective of the complexity or simplicity of the method; what is required is a description of the nucleic acid itself. It is not sufficient to define DNA solely by

its principal biological property, because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any DNA with that biological property. Naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. When one is unable to envision the detailed constitution of a complex chemical compound having a particular function, such as a nucleic acid, so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the nucleic acid has been isolated. Thus, claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived.

The specification as filed describes only *Drosophila* and medfly vitellogenin promoters known in the prior art, which are female-specific regulatory regions, and discloses no male-specific regulatory regions. The evidence shows that vitellogenin promoters regions from mosquitoes were also know in the prior art. However, the specification does not identify or teach how one would make other sex-specific regulatory regions sufficient to describe or enable the generic invention being claimed.

The declaration under 37 CFR 1.132 filed 11/22/04 is insufficient to overcome the rejection of claims 1-14 and 21 based upon a lack of an enabling disclosure and adequate written description as set forth in the last Office action for the reasons set forth above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe

Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1632